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| APPLICATION NO.  | FILING DATE              | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|--------------------------|----------------------|---------------------|------------------|
| 10/691,333   | 10/21/2003               | Michael R. Hale      | VPI99-105DIV 1422   |                  |
| 1473<br>ROPES & GRA                                    | 7590 01/14/2008<br>AVIIP |                      | EXAMINER            |                  |
| PATENT DOCKETING 39/361                                |                          |                      | POWERS, FIONA .     |                  |
| 1211 AVENUE OF THE AMERICAS<br>NEW YORK, NY 10036-8704 |                          |                      | ART UNIT            | PAPER NUMBER     |
|  |                          |                      | 1626                |                  |
|  |                          |                      |                     |                  |
|  |                          |                      | MAIL DATE           | DELIVERY MODE    |
|  |                          |                      | 01/14/2008          | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|  | Application No.  | Applicant(s)   |  |  |  |  |
|--|--|--|--|--|--|--|
|  | 10/691,333   | HALE ET AL.  |  |  |  |  |
| Office Action Summary  | Examiner   | Art Unit   |  |  |  |  |
|  | Fiona T. Powers  | 1626   |  |  |  |  |
| The MAILING DATE of this communication app   | ears on the cover sheet with the c   | orrespondence address  |  |  |  |  |
| Period for Reply   |  |  |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | TE OF THIS COMMUNICATION 6(a). In no event, however, may a reply be tim ill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | I. tely filed the mailing date of this communication. (35 U.S.C. § 133). |  |  |  |  |
| Status   |  |  |  |  |  |  |
| 1) Responsive to communication(s) filed on 14 No   | ovember 2007.  |  |  |  |  |  |
| •  |  |  |  |  |  |  |
| 3) Since this application is in condition for allowan  | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is  |  |  |  |  |  |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  |  |  |  |  |  |  |
| Disposition of Claims  |  |  |  |  |  |  |
| . 4)⊠ Claim(s) <u>1-5 and 7-33</u> is/are pending in the application.  |  |  |  |  |  |  |
| 4a) Of the above claim(s) <u>23-27 and 32</u> is/are withdrawn from consideration.   |  |  |  |  |  |  |
| 5) Claim(s) is/are allowed.  |  |  |  |  |  |  |
| 6)⊠ Claim(s) <u>1-5, 7-22, 28-31 and 33</u> is/are rejected.   |  |  |  |  |  |  |
| 7) Claim(s) is/are objected to.  |  |  |  |  |  |  |
| 8) Claim(s) are subject to restriction and/or election requirement.  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
| Application Papers   |  |  |  |  |  |  |
| 9)☐ The specification is objected to by the Examine  |  |  |  |  |  |  |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.   |  |  |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |  |  |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).   |  |  |  |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |  |  |  |  |  |  |
| Priority under 35 U.S.C. § 119   |  |  |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  |  |  |  |  |  |  |
| a) All b) Some * c) None of:   |  |  |  |  |  |  |
| <ul> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> </ul>   |  |  |  |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage  |  |  |  |  |  |  |
| application from the International Bureau (PCT Rule 17.2(a)).  |  |  |  |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.   |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
| :<br>:   |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
| Attachment(s)  | _  |  |  |  |  |  |
| 1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  Paper No(s)/Mail Date   |  |  |  |  |  |  |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date  5) Notice of Informal Patent Application   |  |  |  |  |  |  |
| Paper No(s)/Mail Date 6) Other:  |  |  |  |  |  |  |

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Receipt is acknowledged of the amendment filed November 14, 2007, which has been entered in the file.

Claims 15 to 17, 28 and 33 are objected to because of the following informalities: claims 15 to 17, 28 and 33 do not end in a period. Appropriate correction is required.

This application contains claims 23 to 27 and 32 drawn to an invention nonelected with traverse in the reply filed on July 25, 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 to 5, 7 to 22, 28 to 31 and 33 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 to 5 and 18 to 20 of U.S.

Patent No. 6,319,946. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims overlap when in the '946 patent Ht is



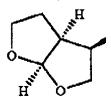
, x is 0 and D is  $C_1$ - $C_6$  alkyl or  $C_2$ - $C_4$  alkenyl that is substituted with Q or  $C_3$ - $C_6$  cycloalkyl optionally substituted with or fused to Q or  $C_5$ - $C_6$  cycloalkenyl optionally substituted with or fused to Q wherein Q contains one substituent selected from  $OR^2$  or  $N(R^2)_2$ . The claims of the instant application and the '946 patent differ in that the claims of the patent are broader. The compounds of the instant application and the patent have the same utility as agents for the treatment of HIV infection. One of ordinary skill in the art would have been motivated to make the claimed compounds with the expectation that additional agents for the treatment of HIV infection would be obtained. The claimed compounds would have been rendered

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obvious by the compounds of the reference in the absence of any unobvious property.

Claims 1 to 5, 7 to 22, 28 to 31 and 33 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4 and 15 to 19 of U.S. Patent No. 6,613,743. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims overlap when in the '743 patent A is  $-R^1$ -Ht,



 $R^1$  is -0-C(0)-, Ht is

and x is 0. The claims of

the instant application and the '743 patent differ in that the claims of the patent are broader. The compounds of the instant application and the patent have the same utility as agents for the treatment of HIV infection. One of ordinary skill in the art would have been motivated to make the claimed compounds with the expectation that additional agents for the treatment of HIV infection would be obtained. The claimed compounds would have been rendered obvious by the compounds of the reference in the absence of any unobvious property.

Claims 1 to 5, 7 to 22, 28 to 31 and 33 are rejected on the ground of nonstatutory obviousness-type double patenting as

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being unpatentable over claims 1 to 7 and 18 to 20 of U.S.

Patent No. 6,617,350. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims overlap when in the '350 patent Ht is

H

, x is 0 and D is  $C_1$ - $C_6$  alkyl or  $C_2$ - $C_4$  alkenyl that is substituted with Q or  $C_3$ - $C_6$  cycloalkyl optionally substituted with or fused to Q or  $C_5$ - $C_6$  cycloalkenyl optionally substituted with or fused to Q wherein Q contains one substituent selected from  $OR^2$  or  $N(R^2)_2$ . The claims of the instant application and the '946 patent differ in that the claims of the patent are broader. The compounds of the instant application and the patent have the same utility as agents for the treatment of HIV infection. One of ordinary skill in the art would have been motivated to make the claimed compounds with the expectation that additional agents for the treatment of HIV infection would be obtained. The claimed compounds would have been rendered obvious by the compounds of the reference in the absence of any unobvious property.

Applicant's arguments filed November 14, 2007 have been fully considered but they are not persuasive. Applicants state

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that the rejection of the claims on the ground of nonstatutory obviousness-type double patenting will be addressed upon the indication of allowable subject matter. As no acceptable terminal disclaimers have been filed, the rejection of the claims on the ground of nonstatutory obviousness-type double patenting must be maintained.

Applicants amendment has overcome the objection to the claims and the rejection under 35 U.S.C. 112,  $2^{nd}$  paragraph presented in the last office action.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fiona T. Powers whose telephone number is 571-272-0702. The examiner can normally be reached on Monday - Friday 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Fiona T. Powers
Primary Examiner
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ftp January 9, 2008